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March 5, 2015

VIA ECF & HAND DELIVERY

Hon. Thomas P. Griesa, U.S.D.J.
United States Courthouse
500 Pearl Street
New York, NY 10007

Re: *Endo Pharmaceuticals Inc., et al. v. Actavis Inc., et al.*, No. 13-cv-0436;
Endo Pharmaceuticals Inc. v. Actavis Inc., et al., No. 12-cv-8985;
Endo Pharmaceuticals Inc., et al., v. Amneal Pharms., LLC, et al., No. 12-cv-8115;
Endo Pharmaceuticals Inc., et al., v. Impax Labs., Inc., No. 13-cv-0435;
Endo Pharmaceuticals Inc., et al., v. Impax Labs., Inc. et al., No. 12-cv-8317;
Endo Pharmaceuticals Inc., v. Par Pharm. Cos., Inc., et al., No. 13-cv-3284;
Endo Pharmaceuticals Inc., v. Ranbaxy Labs. Ltd., et al., No. 13-cv-4343;
Endo Pharmaceuticals Inc., v. Ranbaxy Labs. Ltd., et al., No. 13-cv-8597;
Endo Pharmaceuticals Inc., v. Roxane Labs., No. 13-cv-3288;
Endo Pharmaceuticals Inc., et al., v. Sandoz Inc., No. 12-cv-8318;
Endo Pharmaceuticals Inc., et al., v. Teva Pharms. USA, Inc., et al., No. 12-cv-8060

Dear Judge Griesa:

Your Honor has scheduled a telephone pretrial conference call with the parties for this Friday, March 6, 2015 at noon. We understand that Your Honor scheduled the call in order to discuss the status of the claims to be tried with respect to Endo's '482 patent and '383 patent. We write to provide Your Honor with the current status with respect to those patents, and to raise a couple of additional trial issues for Your Honor's consideration should you wish to address them.

Status of the '482 patent:

Among the claims originally set forth in its complaints, Endo asserted that each of the defendants infringed claims 1 – 4 of the '482 Patent. As we had previously advised the Court, however, there were parallel proceedings instituted by the Patent & Trademark Office ("PTO") in connection with that patent. Those proceedings have now been concluded, and the PTO has



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entered judgment against Endo, cancelling all of those asserted claims of the '482 Patent. *See* Exs. 1 and 2 hereto.

Cancelled patent claims cannot be asserted, and Endo proposed to each defendant that the parties stipulate to a judgment in favor of the defendants and against Endo with respect to its claims for infringement of the '482 patent. Endo has reached agreement with five of the defendants on the terms of the stipulated judgment (Actavis, Amneal, Impax, Ranbaxy, Teva and Thorx), and agreed upon stipulations have been submitted to the Court with respect to those parties (the Court has signed and entered all but two of those stipulations). Endo believes that it will reach agreement with two of the other defendants (Par and Sandoz).

The lone holdout is defendant Roxane, which perversely has refused to accept entry of judgment in its favor. Endo submitted the attached form of order to Roxane on January 8, 2015, and Roxane never had the courtesy to respond. Apparently, Roxane desires to continue litigating the '482 Patent, but to what end, Endo cannot determine.

In order to resolve all matters relating to the '482 Patent and clean up the pleadings, Endo respectfully requests that the Court (a) execute the stipulations pending between Endo and Impax and Thorx, (b) give Endo and Par and Sandoz until March 9, 2015, to submit stipulations of dismissal, and (c) grant judgment in favor of Roxane and against Endo in the form of attached judgment.

Status of the '383 Patent:

In the instant cases relating to Endo's abuse-deterrent, controlled release Opana® ER CRF oxymorphone-containing product, Plaintiffs originally asserted claims 1, 2, 5, 7, and 9 of U.S. Patent No. 8,114,383 ("the '383 patent"). Those same '383 patent claims have been the subject of previous litigation before Judge Stein (SDNY) relating to generic copies of Purdue Pharma's abuse-deterrent, controlled-release OxyContin® product, which contains oxycodone as the active ingredient. The OxyContin® case went to trial in September 2013 where the parties litigated the validity and infringement of claims 1, 2, 5, 7, and 8 of the '383 patent that cover OxyContin® and generic versions thereof. On January 14, 2014, Judge Stein found that while Defendant Teva's generic oxycodone product would infringe the '383 patent claims at issue, claims 1, 2, 5, 7, and 8 were invalid. Claim 8 depends from claim 1 and recites *oxycodone* and its salts as the active ingredient. Claim 9 was not litigated in the OxyContin case because it covers thermoformed dosage forms that contain *oxymorphone* (not oxycodone) as the active ingredient. As a result, Judge Stein's decision never addressed claim 9 of the '383 patent, oxymorphone, or Opana® ER CRF.



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At the February 20, 2014 hearing before this Court, Plaintiffs proposed to stay their claims of infringement regarding claims 1, 2, 5, and 7 of the '383 patent pending disposition of Grunenthal's appeal from Judge Stein's January 14, 2014 decision. February 20, 2014 Hearing Tr. at 30:8-31:13. Defendants never responded to that proposal. To further streamline these cases, however, Plaintiffs are no longer asserting claims 1, 2, 5, and 7 of the '383 patent, and the only '383 patent claim that Plaintiffs will assert at trial is claim 9, as stated in the March 3, 2015 Letter from Erin Sommers to Defendants.¹

Other issues:

Should the Court be willing to discuss them during the upcoming teleconference, Plaintiffs wish to raise the following additional issues:

1. Bar on presentation of duplicative expert witnesses:

At the January 23rd final pretrial conference, Plaintiffs alerted the Court that Defendants had served multiple expert reports with highly similar, highly overlapping subject matter. At that hearing, the Court indicated that it would not hear duplicative testimony, and ordered the parties "to decide who you want to call at trial" to avoid unnecessary depositions. 1/23/15 Hearing Tr. at 161:8. But now, with trial just over two weeks away, Defendants have still refused to disclose whom they actually plan to call at trial. Indeed, Defendants' Trial Witness Lists, served on February 25, still include multiple experts with redundant, overlapping expert reports:

¹ It should be noted that Plaintiffs are not conceding that those claims 1, 2, 5, and 7 are invalid, however. The validity of those claims is the subject of a pending appeal to the Federal Circuit.



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<i>Defense Addressed in Expert Reports</i>	<i>Expert</i>
Infringement	
Method claims	Deer, Kibbe, Mayersohn
Food Effect limitations	Kibbe, Mayersohn, Palmieri, Elmquist
Validity	
Obviousness	Banakar, Kibbe, Mayersohn
On-Sale Bar	Banakar, Kibbe, Mayersohn, Palmieri
Non-Enablement	Banakar, Kibbe, Mayersohn, Palmieri
Written Description	Kibbe, Mayersohn, Palmieri
Indefiniteness	Kibbe, Mayersohn
Secondary considerations of non-obviousness (commercial success)	Blackburn, Hoffman

Defendants repeatedly represented to the Court during the January 23rd hearing that they had no intention of having duplicative expert testimony during trial. *See, e.g.*, Jan. 23, 2015 Hearing Tr. at 142:4-6, 144:13-17, 145:23-25.

Accordingly, Plaintiffs respectfully request that the Court order the Defendants to immediately notify Plaintiffs which witnesses they will call at trial, and if Defendants intend to call more than one witness on infringement or more than one witness regarding validity, then for each of the issues in the chart above, Defendants would have to further identify which particular expert will address the issue.

2. Defendants' Witness Lists:

Plaintiffs object to Defendants' Witness Lists because they fail to comply with Rule 26(a)(3) of the Federal Rules of Civil Procedure. Specifically, Defendants' Witness Lists cumulatively identify those witnesses Defendants expect they “*will or may call live or by deposition* for testimony at trial” (emphasis added), which is contrary to Rule 26(a)(3)’s requirement that a party (1) “separately identify[]” those witnesses Defendants expect to present and those witnesses Defendants may call if the need arises; and (2) designate those witnesses whose testimony Defendants expect to present by deposition. It is unreasonable and prejudicial for Plaintiffs to have to speculate as to which witnesses Defendants expect to call live at trial. Plaintiffs asked Defendants to revise their Lists to comply with Rule 26(a)(3), but to date, they have failed to do so. Plaintiffs request that the Court order Defendants to do so within two days.



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3. Opening Arguments:

We believe that it would be beneficial to the Court for the parties to present brief opening statements at the start of the trial on March 23, in order to give the Court context for the witnesses and testimony they will be presenting. With that in mind, Plaintiffs proposed to Defendants that the parties jointly request that they be permitted to make such opening statements, which would last no more than 1 hour per side—i.e., one hour total for Endo and Grunenthal, and one hour total for all Defendants. We are still awaiting Defendants' response, but given the approaching trial, we request that Your Honor permit opening statements as we have proposed to Defendants.

Sincerely,

/s/ Martin J. Black

Martin J. Black

cc: All Counsel of Record (**VIA ECF**)